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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,005	03/26/2004	Dana P. Gaddy	022438.45889	7761

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EXAMINER	
XIE, XIAOZHEN	

ART UNIT	PAPER NUMBER
1646	

MAIL DATE	DELIVERY MODE
05/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/810,005	GADDY, DANA P.	
	Examiner	Art Unit	
	Xiaozhen Xie	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19 and 21* is/are pending in the application.

4a) Of the above claim(s) *1-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20070213*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, And/Or Claims

The Information Disclosure Statement (IDS) filed 13 February 2007 is acknowledged. Applicant's amendment of the claims filed 13 February 2007 has been entered.

Claims 20 and 22 have been cancelled. Claims 1-19 and 21 are pending. Claims 1-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention. Claims 19 and 21 are under examination.

Claim Objections/Rejections Withdrawn

The objection to claims 19 and 21 for informalities is withdrawn in response to Applicant's amendment of the claims.

The rejection of claims 19-22 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement, is withdrawn in response to Applicant's amendment to limit human inhibin A or B, and cancellation of claims 20 and 22.

The rejection of claims 19-22 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement, is withdrawn in response to Applicant's amendment and cancellation of the claims.

The rejection of claims 19-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuberasampath et al., is withdrawn in response to Applicant's amendment to limit human inhibin A or B, and cancellation of claims 20 and 22.

New Grounds of Rejections

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuberasampath et al. (U.S. Patent No: 5,674,844, issued in 1997), in view of Cassidy et al. (U.S. Patent No: 6,280,474 B1, issued 28 August 2001).

The claims are drawn to a method for increasing cancellous bone strength and bone volume in a human subject comprising administering to the human subject an effective amount of human inhibin A or human inhibin B in a pharmaceutically acceptable carrier (claims 19 and 21).

The '844 patent teaches a method for increasing bone mass or preventing bone loss in an individual, e.g., a human being, afflicted with a bone disease comprising administering to the individual, a therapeutically effective amount of morphogen, including inhibin proteins (column 3, lines 16-25 and column 12, lines 52-54). The '844 patent teaches that the bone disease includes osteoporosis which may result from malignant transformations (column 1, line 62-65). The '844 patent teaches formulations that comprise a pharmaceutically acceptable carrier (column 23, lines 108).

The '844 patent, however, does not teach that the inhibin proteins are inhibin A and inhibin B.

The '474 patent teaches that inhibin A and inhibin B, the two structurally related species, can be used in an implant for tissue repair, e.g., facilitating bone repair and promoting new bone formation (column 11, line 62 through column 12, line 6; column 1, lines 26-39; column 26, lines 62-64).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of the '844 patent, with those of the '474 patent to use inhibin A or inhibin B for increasing bone mass or preventing bone loss in a human afflicted with a bone disease. One of ordinary skill in the art would have been motivated to combine the teachings, because the '844 patent teaches that inhibin proteins can be used to increase bone mass or preventing bone loss, and the '474 patent teaches that inhibin A and inhibin B can be used in an implant to facilitat bone repair and promot new bone formation. Therefore, the teachings provide a reasonable expectation of successfully increasing bone strength and bone volume in a patient.

Applicant argues that the '844 patent suggests that a broad class of proteins, i.e., all morphogens can be used to treat bone loss or increase bone mass in metabolic diseases. Applicant argues that a generic application is not an anticipation. Applicant argues that the identical invention must be shown in as complete detail as is contained in the claim. Applicant argues that the '844 patent claims the morphogen to be a dimeric protein, which is different from human inhibin A and B which are not dimeric proteins, rather they are heterodimeric proteins composed of different A and B subunits. Applicant argues that the "844 patent supports a dimeric protein comprising a sequence

having at least 70% homology with the C-terminal seven-cysteine skeleton of human OP-1 (residues 38-139), however, sequence alignment between the human OP-1 fragment with inhibin α subunit and activin β A subunit which, when combined with the inhibin α subunit, comprises Inhibin A, does not satisfy the 70% homology required by the '844 patent.

Applicant's arguments have been fully considered but have not been found to be persuasive.

As stated above and in the previous office action, the '844 patent specifically discloses that inhibin proteins formulated with a pharmaceutically acceptable carrier can be used to increase bone mass or prevent bone loss in a human patient afflicted with a bone disease, such as osteoporosis resulting from malignant transformations. While the "844 patent teaches OP-1 polypeptides can be used therapeutically to increase bone formation, the "844 patent also supports inhibin proteins for the same therapeutic purpose. Thus, the '844 patent teaches each and every limitation of the claimed invention, either explicitly or inherently.

Conclusion

NO CLAIM IS ALLOWED.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Xiaozhen Xie, Ph.D whose telephone number is 571-272-5569. The examiner can normally be reached on M-F, 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol, Ph.D. can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Xiaozhen Xie, Ph. D.
April 20, 2007

Eileen B. O'Hara

EILEEN B. O'HARA
PRIMARY EXAMINER